SIDE-BY-SIDE COMPARISON OF FDA'S PENDING REGULATIONS,
PROPOSED INDUSTRY RESOLUTION AND ADVISORY COMMITTEE RECOMMENDATIONS

THIS CHART PRESENTS A COMPARISON OF THE PROVISIONS OF THE PROPOSED RESOLUTION WITH THOSE OF THE FDA'S PENDING REGULATIONS AND THE KOOP KESSLER ADVISORY COMMITTEE'S RECOMMENDATIONS. IT SHOULD BE NOTED THAT NONE OF THE PROVISIONS OF THE FDA'S PENDING REGULATIONS (OTHER THAN THOSE ESTABLISHING A NATIONAL MINIMUM AGE AND IMPOSING CARDING REQUIREMENTS) MAY BE NOW ENFORCED: ON APRIL 25, 1997, A FEDERAL COURT, ALTHOUGH DENYING THE TOBACCO INDUSTRY'S MOTION FOR SUMMARY JUDGMENT INVALIDATING THOSE REGULATIONS ON JURISDICTIONAL AND OTHER GROUNDS, ENJOINED FDA FROM IMPLEMENTING ITS ADVERTISING RESTRICTIONS AND STAYED IMPLEMENTATION, PENDING APPEAL, OF THE OTHER REGULATIONS.

I. YOUTH ACCESS / SALES AND DISTRIBUTION

FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
VENDING MACHINES • ALLOWS SALES OF TOBACCO PRODUCTS THROUGH VENDING MACHINES ONLY IN "ADULT ONLY" FACILITIES. (POSSIBLE ADDITIONAL REGULATIONS AFTER 2 YEARS OF FDA MONITORING.)	VENDING MACHINES • BANS ALL SALES OF TOBACCO PRODUCTS THROUGH VENDING MACHINES.	VENDING MACHINES • SAME AS PROPOSED RESOLUTION
DISTRIBUTION THROUGH THE MAIL • BANS DISTRIBUTION OF TOBACCO PRODUCTS THROUGH THE MAIL, EXCEPT PURSUANT TO MAIL ORDER SALES.	DISTRIBUTION THROUGH THE MAIL • SAME, PLUS ONLY PERMITS MAIL ORDER SALES SUBJECT TO PROOF OF AGE AND REQUIRES A REVIEW BY FDA AFTER 2 YEARS TO DETERMINE WHETHER MINORS ARE OBTAINING TOBACCO PRODUCTS THROUGH THE MAIL.	DISTRIBUTION THROUGH THE MAIL • RECOMMENDS BANNING ALL SALES OF TOBACCO PRODUCTS THROUGH MAIL ORDER AND THE INTERNET AND OTHER ELECTRONIC SYSTEMS.
MINIMUM SALES AGE • SETS FEDERAL MINIMUM AGE OF 18, BUT DOES NOT PRECLUDE STATES FROM SETTING A HIGHER MINIMUM AGE	MINIMUM SALES AGE • SAME	MINIMUM SALES AGE • SAME

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FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
EXCISE TAX	EXCISE TAX	EXCISE TAX
• NO PROVISION (FDA DOES NOT HAVE POWER TO LEVY TAXES).	• NO PROVISION, BUT SEE INDUSTRY-FUNDED PROGRAMS AND LOOK-BACK PROVISIONS, BELOW.	• RECOMMENDS INCREASING EXCISE TAXES BY $ PER PACK OF CIGARETTES AND A PROPORTIONATE AMOUNT FOR CIGARS, WITH PERIODIC INCREASES IN TAXES AS WELL AS THE NET PRICES OF TOBACCO PRODUCTS.
INDIVIDUAL CIGARETTES	INDIVIDUAL CIGARETTES	INDIVIDUAL CIGARETTES
• BANS SALES OR DISTRIBUTION OF INDIVIDUAL CIGARETTES.	• SAME	• SAME
PACKS FEWER THAN 20	PACKS FEWER THAN 20	PACKS FEWER THAN 20
• BANS SALES OR DISTRIBUTION OF PACKAGES OF FEWER THAN 20 CIGARETTES.	• SAME	• SAME
IDENTIFICATION	IDENTIFICATION	IDENTIFICATION
• REQUIRES PICTURE IDENTIFICATION FOR ALL PERSONS PURCHASING TOBACCO PRODUCTS. RETAILER MUST CHECK IDENTIFICATION OF ANYONE 26 OR YOUNGER.	• SAME	• SAME, ALSO RECOMMENDS REQUIRING TOBACCO COMPANIES TO PROVIDE MERCHANTS WITH ELECTRONIC SCANNERS WHICH REQUIRE IDENTIFICATION WITH EVERY SALE.
SAMPLING	SAMPLING	SAMPLING
• BANS SAMPLING OF TOBACCO PRODUCTS.	• SAME	• SAME
FACE-TO-FACE TRANSACTIONS	FACE-TO-FACE TRANSACTIONS	FACE-TO-FACE TRANSACTIONS
• REQUIRES RETAILERS TO ENSURE THAT ALL TRANSACTIONS FOR TOBACCO PRODUCTS ARE FACE-TO-FACE.	• SAME	• IMPLICITLY THE SAME
• BANS SELF-SERVICE DISPLAYS, EXCEPT IN "ADULT ONLY " FACILITIES	• SAME, PLUS IN FACILITIES THAT ARE NOT "ADULT ONLY." TOBACCO PRODUCTS MUST BE EITHER BEHIND THE COUNTER OR, IF ON THE COUNTER, NOT VISIBLE TO THE CUSTOMER.	• RECOMMENDS BANNING ALL SELF-SERVICE DISPLAYS.

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II. ADVERTISING AND LABELING

FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
PERMISSIBLE OUTLETS FOR ADVERTISING AND LABELING • PUBLICATIONS, OUTDOOR ADVERTISEMENTS & NONPOINT OF SALE: SETS THE FOLLOWING PERMISSIBLE OUTLETS FOR ADVERTISING AND LABELING: NEWSPAPERS, MAGAZINES, PERIODICALS, OTHER PUBLICATIONS, BILLBOARDS, POSTERS, PLACARDS AND IN NONPOINT OF SALE PROMOTIONAL MATERIAL (INCLUDING DIRECT MAIL ADVERTISING). ⇒ BANS OUTDOOR ADVERTISING WITHIN 1000 FEET OF ANY PLAYGROUND, OR ELEMENTARY OR SECONDARY SCHOOL, INCLUDING OUTWARD FACING RETAIL WINDOW ADVERTISING. ⇒ SEE PROVISIONS ON "OTHER MEDIA," BELOW. ⇒ AUDIO AND VIDEO FORMAT ARE PERMISSIBLE PROVIDED THAT AUDIO IS LIMITED TO WORDS ONLY WITH NO MUSIC OR SOUND EFFECTS AND VIDEO IS LIMITED TO STATIC BLACK TEST ON A WHITE BACKGROUND, WITH NO MUSIC OR SOUND EFFECTS.	PERMISSIBLE OUTLETS FOR ADVERTISING AND LABELING • PUBLICATIONS, OUTDOOR ADVERTISEMENTS & NONPOINT OF SALE: SAME, PLUS IMPOSES THE FOLLOWING ADDITIONAL RESTRICTIONS: ⇒ SAME, PLUS BANS ALL OUTDOOR TOBACCO ADVERTISING, INCLUDING IN ENCLOSED STADIUMS. ⇒ PROHIBITS TOBACCO ADVERTISING ON THE INTERNET UNLESS DESIGNED TO BE INACCESSIBLE IN OR FROM THE UNITED STATES. ⇒ SAME, PLUS POINT OF SALE RESTRICTIONS NOTED BELOW.	PERMISSIBLE OUTLETS FOR ADVERTISING AND LABELING • RECOMMENDS THAT "MARKETING, PROMOTION AND ADVERTISING OF ALL TOBACCO PRODUCTS DIRECTED A PERSONS UNDER AGE 18 SHOULD BE BANNED." (P. AND INCLUDES WITHIN THIS GENERAL BAN, BANS ON BRANDED PROMOTIONAL ITEMS, BRAND-NAME EVEN SPONSORSHIP AND PRODUCT PLACEMENT, AS DISCUSSED BELOW. ALSO STATES THAT "ADVERTISING AND PROMOTION MUST BE ELIMINATED." (P. B1) FURTHER RECOMMENDS THAT "MARKETING, PROMOTION AND ADVERTISING OF ALL TOBACCO PRODUCTS, AND SERVICES, GOODS, AND OTHER ITEMS THAT CARRY TOBACCO BRAND NAMES, LOGS OR IMAGERY," SHOULD BE PROHIBITED. (P. B2, EMPHASIS ADDED).

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FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
RETAILER LICENSING • NO PROVISION	RETAILER LICENSING • ESTABLISHES A MINIMUM FEDERAL STANDARD FOR A RETAILER LICENSING PROGRAM, WITH PENALTIES FOR VIOLATIONS THAT INCLUDE FINES AND THE SUSPENSION OR REVOCATION (ON A SITE-BY-SITE BASIS) OF LICENSE. FEDERAL, STATE AND LOCAL GOVERNMENTS WOULD ENFORCE THROUGH INDUSTRY PAYMENTS.	RETAILER LICENSING • RECOMMENDS LICENSING FOR MANUFACTURERS, DISTRIBUTORS, WHOLESALERS AND IMPORTERS AS WELL AS RETAILERS. ALLOWS ENFORCEMENT BY LOCALITIES AS WELL AS STATES.
RETAILER RESPONSIBILITIES • RETAILERS ARE RESPONSIBLE FOR ENSURING THAT THEIR ACTIVITIES COMPLY WITH THE RULE.	RETAILER RESPONSIBILITIES • SAME	RETAILER RESPONSIBILITIES • RECOMMENDS ONGOING EDUCATION OF RETAILERS AND DISTRIBUTORS.

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III. PROMOTION

FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
NON-TOBACCO BRAND NAMES ON TOBACCO PRODUCTS • BANS NON-TOBACCO NAMES FOR TOBACCO PRODUCTS, UNLESS BOTH THE NON-TOBACCO PRODUCT AND THE TOBACCO PRODUCT WERE SOLD IN THE U.S. PRIOR TO JANUARY 1, 1995.	NON-TOBACCO BRAND NAMES ON TOBACCO PRODUCTS • SAME	NON-TOBACCO BRAND NAMES ON TOBACCO PRODUCTS • NO SPECIFIC RECOMMENDATION
REDEMPTION OF COUPONS THROUGH THE MAIL • BANS SALES OR DISTRIBUTION OF INDIVIDUAL CIGARETTES.	REDEMPTION OF COUPONS THROUGH THE MAIL • SAME	REDEMPTION OF COUPONS THROUGH THE MAIL • SAME
PACKS FEWER THAN 20 • BANS THE DISTRIBUTION OF TOBACCO PRODUCTS THROUGH THE REDEMPTION OF COUPONS EXCEPT IN FACE-TO-FACE TRANSACTIONS WHERE PROOF OF AGE IS REQUIRED	PACKS FEWER THAN 20 • SAME	PACKS FEWER THAN 20 • SAME
TOBACCO BRAND NAMES ON NON-TOBACCO PRODUCTS • BANS THE USE OF TOBACCO BRAND NAMES OR ANY OTHER INDICATION OF TOBACCO BRAND IDENTIFICATION ON NON-TOBACCO PRODUCTS (E.G., T-SHIRTS, HATS, OTHER CLOTHING, GYM BAGS AND TRINKETS).	TOBACCO BRAND NAMES ON NON-TOBACCO PRODUCTS • SAME	TOBACCO BRAND NAMES ON NON-TOBACCO PRODUCTS • SAME
GIFTS AND CONTESTS • NO NON-TOBACCO GIFT OR ITEM MAY BE OFFERED IN CONSIDERATION OF TOBACCO PRODUCT PURCHASE(S) OR BASED ON PROOF OF PURCHASE. • CONTESTS, LOTTERIES AND GAMES OF CHANGE NOT PROHIBITED, BUT THEY MUST FOLLOW THE ADVERTISING RULES AND APPEAR IN "TOMBSTONE" FORMAT.	GIFTS AND CONTESTS • SAME • SAME	GIFTS AND CONTESTS • SAME • SAME
PAID PRODUCT PLACEMENT • NO PROVISION	PAID PRODUCT PLACEMENT • BANS DIRECT AND INDIRECT PAYMENTS FOR TOBACCO PRODUCT PLACEMENT IN MOVIES, TELEVISION PROGRAMS AND VIDEO GAMES.	PAID PRODUCT PLACEMENT • SAME, PLUS RECOMMENDS BANNING ALL TOBACCO PROMOTION IN PUBLIC ENTERTAINMENT.
PAYMENTS FOR "GLAMORIZING" TOBACCO PRODUCTS • NO PROVISION	PAYMENTS FOR "GLAMORIZING" TOBACCO PRODUCTS • BANS DIRECT AND INDIRECT PAYMENTS FOR "GLAMORIZING" TOBACCO USE IN MEDIA APPEALING TO MINORS, INCLUDING MUSICAL PERFORMANCES.	PAYMENTS FOR "GLAMORIZING" TOBACCO PRODUCTS • NO SPECIFIC RECOMMENDATION (BUT SEE PERMISSIBLE OUTLETS, ABOVE, FOR OVERALL PROMOTION RESTRICTIONS).

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FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
• WARNING LABEL SIZE AND LOCATION: NO PROVISION	• WARNING LABEL SIZE AND LOCATION: THE WARNING LABELS MUST APPEAR IN LARGE TYPE, IN BLACK AND WHITE, OCCUPY 25% OF THE FRONT PANEL OF THE PACKAGE (EXCEPT FOR CERTAIN FLIP-TOP BOXES), IN ALTERNATING BLACK-ON-WHITE AND WHITE-ON-BLACK FORMAT, AND APPEAR ON THE UPPER PORTION THEREOF. ALSO INCLUDES SIZE AND LOCATION REQUIREMENTS FOR WARNINGS IN ADVERTISEMENTS.	• WARNING LABEL SIZE AND LOCATION: RECOMMENDS INCREASING THE PROMINENCE OF WARNINGS BY, FOR EXAMPLE, ENLARGING THE WARNING LABEL, USING BRIGHT COLORS AND BOLD TYPE, AND MOVING IT TO THE FRONT CENTER OF THE PACK AND THE MOST PROMINENT SIDE OF THE SMOKELESS TOBACCO PRODUCT PACKAGE.
• NICOTINE-DELIVERY DEVICE: ALL TOBACCO PRODUCT ADVERTISING AND PRODUCT PACKAGING MUST INCLUDE THE FOLLOWING STATEMENT CONTAINING THE PRODUCT'S "ESTABLISHED NAME" AND "A NICOTINE-DELIVERY DEVICE FOR PERSONS 18 OR OLDER."	• NICOTINE-DELIVERY DEVICE: ALL TOBACCO PRODUCT ADVERTISING AND THE SIDE OF EACH PRODUCT PACKAGE MUST INCLUDE THE FOLLOWING STATEMENT: "NICOTINE-DELIVERY DEVICE."	• NICOTINE-DELIVERY DEVICE: NO SPECIFIC RECOMMENDATION
FDA REVIEW OF ADVERTISEMENTS AND LABELS	FDA REVIEW OF ADVERTISEMENTS AND LABELS	FDA REVIEW OF ADVERTISEMENTS AND LABELS
• NO SPECIFIC PROVISION (FDA MIGHT ASSERT THAT ITS GENERAL RULES ON MISBRANDING AND LABELING COULD APPLY.)	• REQUIRES SAMPLES OF ALL NEW ADVERTISING AND LABELING TO BE SUBMITTED TO FDA CONCURRENT WITH THEIR INTRODUCTION INTO THE MARKET.	• FDA AUTHORITY OVER LABELING AND MARKETING IS AN "ANCILLARY FDA REGULATORY ISSUE TO BE CONSIDERED IN ANY PUBLIC HEALTH POLICY." (P. A2).
MANDATORY PRODUCT DISCLAIMERS	MANDATORY PRODUCT DISCLAIMERS	MANDATORY PRODUCT DISCLAIMERS
• NO SPECIFIC PROVISION (FDA MIGHT ASSERT THAT ITS GENERAL RULES ON MISBRANDING AND LABELING COULD APPLY.	• REQUIRES THAT EXISTING PRODUCT DESCRIPTORS SUCH AS "LIGHT" OR "LOW TAR" BE ACCOMPANIED BY A MANDATORY DISCLAIMER IN ADVERTISEMENTS, SUCH AS "BRAND X NOT SHOWN TO BE LESS HAZARDOUS THAN OTHER CIGARETTES." ANY NEW DESCRIPTORS WOULD REQUIRE FDA APPROVAL.	• RECOMMENDS PROHIBITION ON USE OF TERMS SUCH AS "LIGHT, LOW AND MILE," UNLESS SCIENCE SUPPORTS CLAIM AND THE PUBLIC IS PROVEN NOT TO BE MISLED.

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FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
ADULT PERIODICALS • ADULT PERIODICALS ARE PUBLICATIONS FOR WHICH THE YOUR (I.E., UNDER 18) READERSHIP IS NO MORE THAN 15% OF THE TOTAL READERSHIP AND WHICH ARE READ BY FEWER THAN 2 MILLION PERSONS UNDER THE AGE OF 18. WARNINGS • WARNING LABELS: NO PROVISION (WARNING LABEL CONTENT, SIZE AND LOCATION GOVERNED BY THE FEDERAL CIGARETTE LABELING AND ADVERTISING ACT).	ADULT PERIODICALS • SAME WARNINGS • WARNING LABELS: AMENDS THE FEDERAL CIGARETTE LABELING AND ADVERTISING ACT AND THE COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION ACT TO MANDATE NINE NEW ROTATING WARNINGS FOR CIGARETTES AND FOUR FOR SMOKELESS TOBACCO PRODUCTS, INCLUDING: "WARNING: CIGARETTES ARE ADDICTIVE" "WARNING: SMOKING CAN KILL YOU" "WARNING: CIGARETTES CAUSE CANCER" "WARNING: SMOKELESS TOBACCO IS ADDICTIVE" "WARNING: THIS PRODUCT CAN CAUSE MOUTH CANCER" AUTHORIZES FDA TO REQUIRE CHANGES IN THE TEXT OF THESE WARNINGS THROUGH NOTICE AND COMMENT RULEMAKING.	ADULT PERIODICALS • NO SPECIFIC RECOMMENDATION, BUT SEE PERMISSIBLE OUTLETS, ABOVE, FOR OVERALL AD RESTRICTIONS. WARNINGS • WARNING LABELS: RECOMMENDS REQUIRING WARNINGS ON TOBACCO PRODUCTS TO HIGHLIGHT NICOTINE ADDICTION, RISKS FROM SECOND HAND SMOKE AND THE DANGERS OF SMOKING DURING PREGNANCY.

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FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
PERMISSIBLE OUTLETS FOR ADVERTISING & LABELING	PERMISSIBLE OUTLETS FOR ADVERTISING & LABELING	PERMISSIBLE OUTLETS FOR ADVERTISING & LABELING
• POINT OF SALE: RESTRICTS POINT OF SALE IN NON "ADULT ONLY" LOCATIONS TO "TOMBSTONE FORMAT," BLACK TEXT ON WHITE BACKGROUND	• POINT OF SALE: SAME, PLUS IMPOSES THE FOLLOWING ADDITIONAL RESTRICTIONS ON POINT OF SALE ADVERTISING IN NON "ADULT ONLY" FACILITIES:	• POINT OF SALE: NO SPECIFIC RECOMMENDATION
-- NO PROVISION	-- PROHIBITS POINT OF SALE TOBACCO ADVERTISEMENTS WITHIN 2 FEET OF A CANDY DISPLAY.	
-- NO PROVISION	-- AUDIO AND VIDEO FORMATS OTHERWISE PERMITTED UNDER THE FDA RULE MAY BE DISTRIBUTED TO ADULT CONSUMERS AT POINT OF SALE BUT MAY NOT BE PLAYED OR SHOWN AT POINT OF SALE (I.E., NO "STATE VIDEO DISPLAYS").	
-- NO PROVISION	-- REGULATES THE NUMBER OF PERMISSIBLE POINT OF SALE TOBACCO ADVERTISEMENTS AT EACH LOCATION WHERE TOBACCO PRODUCTS ARE SOLD.	
-- NO PROVISION	-- LIMITS THE SIZE OF POINT OF SALE ADVERTISEMENTS.	
• OTHER MEDIA: ADVERTISERS MUST GIVE 30 DAYS NOTICE TO FDA BEFORE USING ANY OTHER MEDIA.	• OTHER MEDIA: SAME	• OTHER MEDIA: NO SPECIFIC RECOMMENDATION
TOMBSTONE ADVERTISING AND LABELING	TOMBSTONE ADVERTISING AND LABELING	TOMBSTONE ADVERTISING AND LABELING
• ADVERTISING AND LABELING (WITH THE EXCEPTION OF PACKAGE LABELS) IN PERMISSIBLE OUTLETS MAY ONLY BE IN BLACK TEXT ON A WHITE BACKGROUND (NO IMAGERY OR COLORS), EXCEPT FOR "ADULT PERIODICALS," AS DEFINED BELOW AND IN "ADULT ONLY" FACILITIES.	• SAME	• NO SPECIFIC RECOMMENDATION, BUT SEE PERMISSIBLE OUTLETS, ABOVE, FOR ABOVE OVERALL AD RESTRICTIONS.
USE OF HUMAN IMAGES & CARTOON CHARACTERS	USE OF HUMAN IMAGES & CARTOON CHARACTERS	USE OF HUMAN IMAGES & CARTOON CHARACTERS
• NO PROVISION	• BANS THE USE OF HUMAN IMAGES AND CARTOON CHARACTERS (I.E., THE MARLBORO MAN AND JOE CAMEL) IN ALL TOBACCO ADVERTISING AND ON TOBACCO PACKAGES.	• NO SPECIFIC RECOMMENDATION, BUT SEE PERMISSIBLE OUTLETS, ABOVE FOR OVERALL AD RESTRICTIONS.

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FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
• BRAND NAME SPONSORSHIP: ⇒ BANS BRAND NAME SPONSORSHIP OF ATHLETIC, MUNICIPAL, ARTISTIC OR OTHER SOCIAL OR CULTURAL EVENTS. ⇒ ALLOWS CORPORATE SPONSORSHIP OF ANY EVENT IF THE TOBACCO COMPANY NAME WAS IN EXISTENCE ON JANUARY 1, 1995.	• BRAND NAME SPONSORSHIP: ⇒ SAME ⇒ SAME	• BRAND NAME SPONSORSHIP: ⇒ SAME ⇒ SILENT ON CORPORATE SPONSORSHIP.
TEAMS AND ENTRIES IN SPONSORED EVENTS: • PROHIBITS TOBACCO PRODUCT IDENTIFICATION ON ENTRIES AND TEAMS IN SPONSORED EVENTS (SUCH AS STOCK CARS AND THEIR DRIVERS AND CREWS).	TEAMS AND ENTRIES IN SPONSORED EVENTS: • SAME	TEAMS AND ENTRIES IN SPONSORED EVENTS: • NO SPECIFIC RECOMMENDATION (BUT SEE BRAND NAME SPONSORSHIP BAN AND GENERAL BAN ON ALL PROMOTION OF TOBACCO PRODUCTS, SERVICES OR GOODS THAT CARRY BRAND NAMES, LOGS OR IMAGERY, UNDER PERMISSIBLE OUTLETS ABOVE).

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IV. REGULATION OF TOBACCO PRODUCT DEVELOPMENT AND MANUFACTURING

FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
"REDUCED RISK" TOBACCO PR • THE FDA DECLINED TO ADDRESS REDUCED RISK PRODUCTS IN ITS FINAL RULE, ALTHOUGH THE AGENCY BELIEVES IT ASSERTION OF JURISDICTION WOULD PERMIT IT TO DO SO IN THE FUTURE.	"REDUCED RISK" TOBACCO PR • BARS MANUFACTURERS FROM MAKING CLAIMS THAT STATE OR IMPLY A REDUCED HEALTH RISK ABSENT A DEMONSTRATION TO FDA THAT THE PRODUCT SIGNIFICANTLY REDUCES THE RISK TO HEALTH.	"REDUCED RISK" TOBACCO PR • THE REPORT REPEATEDLY ASSERTS A "NO LIMITATIONS" POLICY ON FDA'S AUTHORITY TO REGULATE NICOTINE, OTHER CONSTITUENTS AND INGREDIENTS OF TOBACCO PRODUCTS.
⇒ NO SPECIFIC PROVISION	⇒ REQUIRES FDA APPROVAL OF ALL HEALTH CLAIMS, AS WELL AS THE CONTENT AND PLACEMENT THEREOF IN ADVERTISEMENTS.	
⇒ NO SPECIFIC PROVISION	⇒ AUTHORIZES FDA TO PERMIT SCIENTIFICALLY BASED HEALTH CLAIMS ABOUT "LESS HAZARDOUS TOBACCO PRODUCTS" AND TO EXEMPT SUCH PRODUCTS FROM THE ADVERTISING RESTRICTIONS IF FDA DETERMINES SUCH EXCEPTIONS WOULD PROMOTE THE PUBLIC HEALTH.	⇒ SEE BULLET ABOVE.
⇒ NO SPECIFIC PROVISION	⇒ REQUIRES MANUFACTURERS TO NOTIFY FDA OF ANY TECHNOLOGY THEY POSSESS THAT REDUCES THE RISKS ASSOCIATED WITH TOBACCO PRODUCTS, AND TO CROSS LICENSE SUCH TECHNOLOGY TO OTHER TOBACCO MANUFACTURERS	⇒ RECOMMENDS THAT FRAMEWORK FOR FDA REGULATIONS SHOULD "BRING TO MARKET LESS DANGEROUS PRODUCTS AND EXPOSE KNOW SCIENCE REQUIRING "LESS HAZARDOUS" DELIVERY SYSTEMS IN FULL PUBLIC VIEW," (P. A4), AND SHOULD BE DONE IN A MANNER THAT DOES MAKE THE DEVELOPMENT OF SUCH PRODUCTS DIFFICULT AND THAT ENCOURAGES MAXIMUM OVERALL REDUCTION IN DISEASE.
CLASSIFICATION • FDA DECLINED TO CLASSIFY TOBACCO PRODUCTS IN ITS FINAL RULE BASED ON THE NUMEROUS PROCEDURAL STEPS REQUIRED PRIOR TO SUCH A CLASSIFICATION, BUT INDICATED AN INTENTION AND WOULD BE REQUIRED TO DO SO IN A FUTURE RULEMAKING PROCEEDING.	CLASSIFICATION • TOBACCO PRODUCTS WILL BE CLASSIFIED AS A NEW SUBCATEGORY OF CLASS II MEDICAL DEVICES.	CLASSIFICATION • NO SPECIFIC RECOMMENDATION (BUT SEE THE "NO LIMITATIONS" POLICY OF FDA REGULATION SUGGESTS THAT FDA WOULD UNDERGO CLASSIFICATION PROCEDURES).

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f S PENDING REGULATIONS	PROPOSED OLUTION	ADVISORY COMMITTEE RECOMMEN ION
REGULATION OF NICOTINE AND OTHER CONSTITUENTS • THE FDA RULE DECLINED TO ADDRESS THE REDUCTION OF NICOTINE LEVELS OR OTHER PRODUCT MODIFICATIONS IN ITS FINAL RULE, ALTHOUGH THE AGENCY BELIEVES ITS ASSERTION OF JURISDICTION WOULD PERMIT IT TO DO SO IN THE FUTURE.	REGULATION OF NICOTINE AND OTHER CONSTITUENTS • FDA SHALL BE EXPRESSLY AUTHORIZED TO IMPOSE STANDARDS FOR REDUCING THE HARD CAUSED BY TOBACCO PRODUCTS, INCLUDING REDUCING THE LEVELS OF NICOTINE AND OTHER CIGARETTE CONSTITUENTS. FDA IS PROHIBITED FROM BANNING THE SALE OF TRADITIONAL TOBACCO PRODUCTS TO ADULTS; BUT THE ELIMINATION OF NICOTINE (AFTER 12 YEARS) OR OTHER CONSTITUENTS FOUND TO BE HARMFUL BY FDA WOULD NOT BE DEEMED A BAN.	REGULATION OF NICOTINE AND OTHER CONSTITUENTS • RECOMMENDS THAT NICOTINE BE REGULATED IN A WAY CONSISTENT WITH ALL OTHER NICOTINE DELIVERY SYSTEMS (SUCH AS GUM, PATCHES, INHALERS). RECOMMENDS THAT FDA BE EXPRESSLY AUTHORIZED TO IMPOSE STANDARDS FOR PHASING OUT THE LEVELS OF NICOTINE AND REMOVING OTHER CIGARETTE INGREDIENTS AND CONSTITUENTS.
• NO SPECIFIC PROVISION	• FOR 12 YEARS FOLLOWING ENACTMENT, PERMITS FDA, UNDER A "SUBSTANTIAL EVIDENCE" STANDARD APPLICABLE TO ALL PERMANENCE STANDARDS FOR MEDICAL DEVICES, TO REQUIRE THE GRADUAL REDUCTION (BUT NO THE ELIMINATION) OF NICOTINE YIELDS AND THE REDUCTION OR ELIMINATION OF OTHER CONSTITUENTS OR COMPONENTS FOUND TO BE HARMFUL PROVIDED THAT: THE MODIFICATION WILL SIGNIFICANTLY REDUCE HEALTH RISKS TO CONSUMERS OF TOBACCO PRODUCTS, IS TECHNOLOGICALLY FEASIBLE, AND WILL NOT RESULT IN A SIGNIFICANT DEMAND FOR CONTRABAND OR "BLACK MARKET" TOBACCO PRODUCTS.	• RECOMMENDS NO LIMITATION, EITHER SUBSTANTIVE OR PROCEDURAL, ON FDA AUTHORITY TO REGULATE NICOTINE AND OTHER CONSTITUENTS. "THE BEST SCIENCE, INFORMATION AND HEALTH POLICY, NOT AN ARBITRARY DEADLINE, SHOULD DRIVE FDA REGULATORY TIME" (P. A3). RECOMMENDS THAT "LION'S SHARE OF THE BURDEN OF PROOF SHOULD REST WITH THE TOBACCO INDUSTRY IN ALL AREAS OF JURISDICTION." (P. A3)
• STANDARDS FOR MEDICAL DEVICES PROMULGATED PURSUANT TO "INFORMAL" NOTICE AND COMMENT RULEMAKING.	• MODIFICATIONS REQUIRE FORMAL RULEMAKING.	
• NO SPECIFIC PROVISION	• AFTER 12 YEARS, PERMITS FDA, UNDER A "PREPONDERANCE OF THE EVIDENCE" STANDARD, TO REQUIRE THE ELIMINATION OF NICOTINE AND THE REDUCTION OR ELIMINATION OF OTHER CONSTITUENTS OR COMPONENTS FOUND TO BE HARMFUL PROVIDED THAT A MODIFIED VERSION OF THE STANDARDS DESCRIBED ABOVE ARE MET.	
• NO SPECIFIC PROVISION	• BANS THE SALE IN THE UNITED STATES OF CIGARETTES WITH A "TAR" YIELD GREATER THAN 12MG. (AS MEASURED BY CURRENT FTC METHODOLOGY) THREE YEARS AFTER ENACTMENT	• NO SPECIFIC RECOMMENDATION (BUT SEE "NO-LIMITATIONS" POLICY ON CONSTITUENT ELIMINATION, ABOVE).

Source: https://www.industrydocuments.ucsf.edu/docs/yygy0000

FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
REGULATION OF NICOTINE AND OTHER CONSTITUENTS • NO SPECIFIC PROVISION	REGULATION OF NICOTINE AND OTHER CONSTITUENTS • ESTABLISHES A SCIENTIFIC ADVISORY COMMITTEE TO STUDY THE EFFECTS OF ALTERING NICOTINE YIELDS, TO DETERMINE WHETHER THERE IS A THRESHOLD LEVEL BELOW WHICH NICOTINE YIELDS DO NOT PRODUCE DRUG DEPENDENCE, AND TO REVIEW OTHER SAFETY, DEPENDENCE AND HEALTH ISSUES.	REGULATION OF NICOTINE AND OTHER CONSTITUENTS • ENCOURAGES RESEARCH ON THE EFFECTS OF NICOTINE IN CHILDREN AND YOUTH. RECOMMENDS EXCHANGE CONFERENCES BETWEEN PUBLIC AND PRIVATE RESEARCHERS ON NICOTINE AND OTHER TOBACCO PRODUCT COMPONENTS.
• NO SPECIFIC PROVISION	• REQUIRES FDA TO PROMULGATE A RULE GOVERNING TESTING, REPORTING AND DISCLOSURE OF CONSTITUENTS, INCLUDING, BUT NOT LIMITED TO, "TAR," NICOTINE AND CARBON MONOXIDE.	• RECOMMENDS THAT FDA HAVE THE AUTHORITY TO TEST NICOTINE LEVELS BY BRAND BASED ON "THE BEST SCIENCE," TO REGULATE OTHER "TOXIC CONSTITUENTS" AS WELL AS NICOTINE, AND GENERALLY THE "AUTHORITY TO REGULATE, DISCLOSURE, AND IF NECESSARY PROHIBIT OTHER CONSTITUENTS AND INGREDIENTS." (P. A2)
GMP'S • EFFECTIVE AUGUST 28, 1998, SUBJECTS MANUFACTURERS TO GOOD MANUFACTURING PRACTICES (GMP'S) APPLICABLE TO DEVICES.	GMP'S • SUBJECTS MANUFACTURERS TO GOOD MANUFACTURING PRACTICE STANDARDS (GMP'S) TAILORED FOR TOBACCO PRODUCTS WHICH ARE COMPARABLE TO THOSE APPLICABLE TO OTHER FDA REGULATED PRODUCTS.	GMP'S • NO SPECIFIC RECOMMENDATION, BUT NOTE THAT THE "NO LIMITATIONS" POLICY ON FDA AUTHORITY AND THE REPORT'S INCLUSION OF "ANCILLARY FDA REGULATORY ISSUES" (P. A2) WOULD LIKELY COVER THIS AREA.
RECORDS AND REPORTS • SUBMISSION: MANUFACTURERS ARE SUBJECT TO THE REPORTING AND RECORD KEEPING REQUIREMENTS GENERALLY APPLICABLE TO DEVICE MANUFACTURERS.	RECORDS AND REPORTS • SUBMISSIONS: SAME	RECORDS AND REPORTS • SUBMISSIONS: NO SPECIFIC RECOMMENDATION, BUT NOTE THAT THE "NO LIMITATIONS" POLICY ON FDA AUTHORITY AND THE REPORT'S INCLUSION OF "ANCILLARY FDA REGULATORY ISSUES" (P. A2) WOULD LIKELY COVER THIS AREA.
• INSPECTIONS: AS PROVIDED IN DEVICE REGULATIONS.	• SUBMISSIONS: SAME	• SUBMISSIONS: NO SPECIFIC RECOMMENDATION, BUT NOTE THAT THE "NO LIMITATIONS" POLICY ON FDA AUTHORITY AND THE REPORT'S INCLUSION OF "ANCILLARY FDA REGULATORY ISSUES" (P. A2) WOULD LIKELY COVER THIS AREA.
• INSPECTIONS: AS PROVIDED IN DEVICE REGULATIONS.	• INSPECTIONS: SAME	• INSPECTIONS: NO SPECIFIC RECOMMENDATION, BUT NOTE THAT THE "NO LIMITATIONS" POLICY ON FDA AUTHORITY AND THE REPORT'S INCLUSION OF "ANCILLARY FDA REGULATORY ISSUES" (P. A2) WOULD LIKELY COVER THIS AREA.

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[illegible]'S PENDING REGULATIONS	PROPOSED [illegible]SOLUTION	ADVISORY COMMITTEE RECOMMEN[illegible]TION
INGREDIENTS: • INGREDIENTS DISCLOSURE: NO COMPARABLE PROVISION IN CURRENT RULE, ALTHOUGH FDA BELIEVES IT COULD PROMULGATE A RULE ON THIS TOPIC IN THE FUTURE. UNDER THE FEDERAL CIGARETTE LABELING AND ADVERTISING ACT AND THE COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION ACT, MANUFACTURERS ARE REQUIRED TO SUBMIT ONLY AGGREGATED INGREDIENT INFORMATION ON AN INDUSTRY-WIDE BASIS, NOT BRAND SPECIFIC INFORMATION, TO IIIIS.	INGREDIENTS: • INGREDIENTS DISCLOSURE: REQUIRES MANUFACTURERS TO SUBMIT TO FDA A LIST OF ALL ADDED INGREDIENTS, BY BRAND AND BY AMOUNT.	INGREDIENTS: • INGREDIENTS DISCLOSURE: SEE REDUCED RISK PRODUCTS, ABOVE FOR DISCUSSION OF THE NO LIMITATIONS POLICY ON FDA AUTHORITY TO REGULATE, DISCLOSE, AND IF NECESSARY PROHIBIT NICOTINE AND OTHER CONSTITUENTS AND INGREDIENTS.
• SAFETY ASSESSMENT: NO COMPARABLE PROVISION IN CURRENT RULE. UNDER THE FEDERAL CIGARETTE LABELING AND ADVERTISING ACT AND THE COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION ACT, IIIIS IS AUTHORIZED TO STUDY THE SAFETY OF INGREDIENTS AND REPORT SUCH RESULTS TO CONGRESS.	• SAFETY ASSESSMENT: WITHIN 5 YEARS OF ENACTMENT, REQUIRES MANUFACTURERS TO PERFORM AND SUBMIT TO FDA A SAFETY ASSESSMENT FOR EACH INGREDIENT ADDED TO TOBACCO PRODUCTS. FDA MAY PROHIBIT USE OF INGREDIENTS WHICH IT FINDS TO BE HARMFUL AS USED.	• SAFETY ASSESSMENT: SEE FIRST BULLET, ABOVE.
• PUBLIC DISCLOSURE: NO PROVISION IN CURRENT RULE. NO DISCLOSURE TO CONSUMERS IS REQUIRED. IN THE PREAMBLE TO THE FINAL RULE, FDA NOTED THAT IT BELIEVES IT HAS THE AUTHORITY TO REQUIRE THE LABELING OR LISTING OF SUBSTANCES PRESENT OR DELIVERY BY CIGARETTES AND SMOKELESS TOBACCO, BUT DECLINED TO DO SO AT THIS TIME.	• PUBLIC DISCLOSURE: REQUIRES MANUFACTURERS TO DISCLOSE INGREDIENT INFORMATION TO THE PUBLIC, TO THE SAME DEGREE AS THE FOOD LABELING MODEL.	• PUBLIC DISCLOSURE: SEE FIRST BULLET, ABOVE.

Source: https://www.industrydocuments.ucsf.edu/docs/yygy0000

V. ENFORCEMENT, PENALTIES AND FUNDING

FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
INDUSTRY-FUNDED PROGRAMS • NO SPECIFIC PROVISION. IN THE PREAMBLE, THE AGENCY INDICATED THAT IT MAY IN THE FUTURE ATTEMPT TO REQUIRE MANUFACTURERS TO NOTIFY YOUTH ABOUT THE HEALTH RISKS OF SMOKING UNDER SECTION 518(A).	INDUSTRY-FUNDED PROGRAMS • REQUIRES INDUSTRY TO PAY A TOTAL SUM OVER 25 YEARS OF $368.5 BILLION DOLLARS (SUBJECT TO ADJUSTMENTS), FROM WHICH VARIOUS PUBLIC HEALTH INITIATIVES WILL BE FUNDED. THE ATTORNEYS GENERAL HAVE PROPOSED THAT A PORTION OF THE FUNDS COLLECTED BE DIRECTED TO THE FOLLOWING PAYMENTS, ALTHOUGH THE ULTIMATE TOTALS AND RECIPIENTS WILL BE DECIDED BY CONGRESS AND THE PRESIDENT. ⇒ $300M PER YEAR TO SUPPORT FDA'S ENFORCEMENT EFFORTS, INCLUDING STATE ENFORCEMENT INCENTIVES.. ⇒ $75M TO $125M PER YEAR TO FUND STATE AND LOCAL TOBACCO CONTROL EFFORTS ⇒ $1B TO $1.5B PER YEAR FOR CESSATION PROGRAMS ⇒ $125 TO $225M PER YEAR TO SUPPORT PROGRAMS BY IIIIS TO REDUCE TOBACCO USAGE ⇒ $100M PER YEAR TO FUND RESEARCH AND DEVELOPMENT OF METHODS DESIGNED TO DISCOURAGE TOBACCO USE AND TO ASSIST WITH TOBACCO CESSATION ⇒ $500M PER YEAR TO FIND A PUBLIC EDUCATION CAMPAIGN DESIGNED TO DISCOURAGE AND DEGLAMORIZE THE USE OF TOBACCO PRODUCTS	INDUSTRY-FUNDED PROGRAMS • RECOMMENDS THAT FINES FROM PERFORMANCE STANDARD VIOLATIONS, A $2 PER PACK INCREASE IN CIGARETTE EXCISE TAXES AND OTHER UNSPECIFIED FUNDS FROM THE INDUSTRY WOULD SUPPORT THE PROGRAMS BELOW. ⇒ ENFORCEMENT EFFORTS BY FEDERAL, STATE AND LOCAL GOVERNMENT AGENCIES ⇒ SUPPORT OF STATE AND LOCAL ANTI-TOBACCO EFFORTS ⇒ RESEARCH AND IMPLEMENTATION OF CESSATION PROGRAMS AND PROGRAMS AIMED AT REDUCING TOBACCO CONSUMPTION, EMPHASIZING CHILDREN AND ADOLESCENTS AS WELL AS PRE AND POST-NATAL PROGRAMS. ⇒ A $500 MILLION ANNUAL PAYMENT OF COUNTER-ADVERTISING IN ALL MEDIA MARKETS. ⇒ SCHOOL-BASED TOBACCO PREVENTION PROGRAMS AND PUBLIC AWARENESS PROGRAMS DIRECTED AT SPECIFIC POPULATIONS.

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F 3 PENDING REGULATIONS	PROPOSED OLUTION	ADVISORY COMMITTEE RECOMMEN ON
INDUSTRY-FUNDED PROGRAMS • NO PROVISION	INDUSTRY-FUNDED PROGRAMS • $75M PER YEAR FOR 10 YEARS TO COMPENSATE EVENTS, TEAMS AND ENTRIES FOR LOSSES IN SPONSORSHIP. • PROVIDES THAT PAYMENTS ARE TO BE TREATED AS "ORDINARY AND NECESSARY" BUSINESS EXPENSES.	INDUSTRY-FUNDED PROGRAMS • NO RECOMMENDATION • A NEW NON-PROFIT CORPORATION TO SUPPORT TOBACCO PREVENTION AND CONTROL PROGRAMS. • A VARIETY OF RESEARCH INITIATIVES • TOBACCO COMPANY PAYMENTS SHOULD NOT BE TAX-DEDUCTIBLE. EXCISE TAX PROPOSAL WOULD PRESUMABLY NOT INCREASE THE TAXABLE INCOME OF THE MANUFACTURER.
ENFORCEMENT • PROVIDES FOR ENFORCEMENT BY THE DEPARTMENT OF JUSTICE AND FDA PURSUANT TO THE POWERS SET FORTH UNDER THE FEDERAL, DRUG AND COSMETIC ACT.	ENFORCEMENT • SAME, PLUS THE PROPOSAL CONTEMPLATES GIVING STATES CERTAIN ABILITIES TO BRING ENFORCEMENT ACTIONS.	ENFORCEMENT • RECOMMENDS AGGRESSIVE ENFORCEMENT OF FEDERAL STATE AND LOCAL TOBACCO CONTROL LAWS. • RECOMMENDS ESTABLISHMENT OF NON-GOVERNMENTAL ORGANIZATIONS TO SERVE AS WATCHDOG AGENCIES OVERSEEING GOVERNMENT ENFORCEMENT. • RECOMMENDS ALLOWING INDIVIDUALS TO BRING SUITE TO ENFORCE FEDERAL, STATE AND LOCAL TOBACCO CONTROL LAWS.
COMPLIANCE PROGRAMS • NO PROVISION	COMPLIANCE PROGRAMS • REQUIRES MANUFACTURERS TO CREATE CORPORATE COMPLIANCE PLANS AND PROVIDE INTERNAL INCENTIVES FOR REDUCING YOUTH ACCESS AND TOBACCO USE INCIDENCE AND FOR DEVELOPING "REDUCED RISK" TOBACCO PRODUCTS.	COMPLIANCE PROGRAMS • NO RECOMMENDATION, BUT RECOMMENDS ESTABLISHING A FEDERAL OVERSIGHT BOARD TO INVESTIGATE ALL MATTERS RELATED TO THE TOBACCO INDUSTRY.

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FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
DOCUMENT DISCLOSURE • NO SPECIFIC PROVISION	DOCUMENT DISCLOSURE • REQUIRES MANUFACTURERS TO DISCLOSE CONFIDENTIAL INTERNAL LABORATORY RESEARCH AND OTHER DOCUMENTS TO FDA, PRIVATE LITIGANTS AND THE PUBLIC, SUBJECT TO CERTAIN TRADE SECRET AND PRIVILEGE PROTECTIONS. • ESTABLISHES A NATIONAL TOBACCO DOCUMENT DEPOSITORY, AS DESCRIBED ON PAGES 18 AND 64-68 OF THE PROPOSED RESOLUTION.	DOCUMENT DISCLOSURE • RECOMMENDS MANDATORY DISCLOSURE OF ALL INTERNAL TOBACCO COMPANY DOCUMENTS WHICH BEAR UPON THE PUBLIC HEALTH INCLUDING, BUT NOT LIMITED TO TECHNICAL HEALTH/SAFETY DATA, MARKETING RESEARCH AND DOCUMENTS RELATING TO THE EFFECTS OF SECOND HAND SMOKE. PROPOSES A POSSIBLE EXCEPTION FOR TRADE SECRETS WHICH DO NOT HAVE HEALTH IMPLICATIONS. ALSO RECOMMENDS OBTAINING INDUSTRY RESEARCH ON NICOTINE AND OTHER TOBACCO PRODUCT COMPONENTS AS THEY EFFECT CHILDREN AND YOUTH. REQUIRES WAIVER OF ANY CLAIMS OF ATTORNEY-CLIENT AND WORK-PRODUCT PRIVILEGES FOR ANY DOCUMENTS EXCEPT THOSE RECENTLY CREATED. • RECOMMENDS ESTABLISHING A FEDERALLY FUNDED DATA COLLECTION BANK TO FACILITATE ACCESS TO DOCUMENTS BY REGULATORS, HEALTH GROUPS AND LITIGANTS.
CIVIL LIABILITY • NO PROVISION (FDA HAS NO AUTHORITY)	CIVIL LIABILITY • CONTAINS PROVISIONS GOVERNING ACTIONS FOR CIVIL LIABILITY RELATED TO TOBACCO AND HEALTH. (SEE PAGES 39-42 IN THE PROPOSED RESOLUTION.)	CIVIL LIABILITY • CALLS FOR FULL PRESERVATION OF ALL CURRENTLY AVAILABLE AVENUES OF LITIGATION.

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S PENDING REGULATIONS	PROPOSED SOLUTION	ADVISORY COMMITTEE RECOMMEN TION
PENALTIES • PROVIDES FOR INJUNCTIVE RELIEF, SEIZURES, AND CIVIL AND CRIMINAL PENALTIES UNDER THE PENALTY SCHEME OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT.	PENALTIES • SAME, PLUS IMPOSES THE FOLLOWING:	PENALTIES • SAME, PLUS IMPOSES THE FOLLOWING:
⇒ NO PROVISION	⇒ ADDITIONAL PENALTIES OF UP TO $10 MILLION PER VIOLATION FOR VIOLATIONS OF THE OBLIGATION TO DISCLOSE RESEARCH ABOUT HEALTH EFFECTS AND INFORMATION ABOUT THE TOXICITY OF NON TOBACCO INGREDIENTS AND CONSTITUENTS	⇒ NO RECOMMENDATION
⇒ NO PROVISION	⇒ ADDITIONAL PENALTIES FOR VIOLATION OF THE RETAIL LICENSING REQUIREMENTS	⇒ ADDITIONAL PENALTIES FOR VIOLATION OF THE RETAIL LICENSING REQUIREMENTS
⇒ NO PROVISION	⇒ ADDITIONAL FINES FOR VIOLATION OF COMPLIANCE PROGRAMS; AND	⇒ ADDITIONAL FINES FOR VIOLATION OF COMPLIANCE PROGRAMS; AND
⇒ NO PROVISION	⇒ ADDITIONAL SURCHARGES FOR FAILURE TO MEET THE TARGETS FOR REDUCTION OF YOUTH TOBACCO USE	⇒ ADDITIONAL SURCHARGES FOR FAILURE TO MEET THE TARGETS FOR REDUCTION OF YOUTH TOBACCO USE

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FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
LOOK-BACK PROVISION • NO COMPARABLE PROVISION. AGENCY WILL MONITOR YOUTH TOBACCO USE INCIDENCE AND MAY ISSUE ADDITIONAL REGULATIONS IN THE FUTURE. NO PERCENTAGES FOR REDUCTION ESTABLISHED.	LOOK-BACK PROVISION • PROVIDES THE FOLLOWING TARGETS FOR THE REDUCTION OF UNDERAGE TOBACCO USE AND IMPOSES MANDATORY SURCHARGES, WITH JOINT AND SEVERAL LIABILITY APPORTIONED BY MARKET SHARE, OF $80 MILLION PER PERCENTAGE POINT UP TO $2 BILLION PER YEAR ON THE TOBACCO MANUFACTURERS IF THESE TARGETS ARE NOT ACHIEVED AND MAINTAINED: YEAR AFTER ENACTMENT — REQUIREMENT 5-6 YEARS — 30% REDUCTION 7-9 YEARS — 50% REDUCTION 10/YEARS — 60% REDUCTION	LOOK-BACK PROVISION • RECOMMENDS TARGETS FOR THE REDUCTION OF UNDERAGE TOBACCO USE AT LEAST AS STRICT AS THOSE BELOW. NONDEDUCTIBLE PENALTIES TO TOBACCO MANUFACTURERS FOR FAILING TO MEET THESE GOALS ARE UNSPECIFIED, BUT WOULD BE APPROXIMATELY $80 MILLION PER PERCENTAGE POINT BY WHICH THE TARGET WAS NOT MET. PENALTIES SHOULD BE ASSESSED ON A COMPANY-BY-COMPANY BASIS TO THE EXTENT POSSIBLE AND SHOULD REDUCE TOTAL REVENUE AND SHAREHOLDER VALUE. PENALTIES SHOULD NOT BE CAPPED AND SHOULD INCLUDE NON-FINANCIAL MEASURES, SUCH AS REQUIRING PLAIN PACKAGING. RECOMMENDS SIMILAR GOALS AND PENALTIES FOR SMOKELESS TOBACCO AND OTHER TOBACCO PRODUCTS. YEAR AFTER ADOPTION — REQUIREMENT 2 YEARS — 15% REDUCTION 3 YEARS — 20% REDUCTION 4 YEARS — 25% REDUCTION 5 YEARS — 30% REDUCTION 6 YEARS — 40% REDUCTION 7 YEARS — 50% REDUCTION 8 YEARS — 55% REDUCTION 9 YEARS — 60% REDUCTION 10 YEARS — 65% REDUCTION

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S PENDING REGULATIONS	PROPOSED OLUTION	ADVISORY COMMITTEE RECOMMEN ION
ENVIRONMENTAL TOBACCO SMOKE • NO PROVISION	ENVIRONMENTAL TOBACCO SMOKE • RESTRICTS INDOOR SMOKING IN "PUBLIC FACILITIES" TO VENTILATED AREAS WITH SYSTEMS THAT: ⇒ EXHAUST THE AIR DIRECTLY OUTSIDE ⇒ MAINTAIN SMOKING AREA AT NEGATIVE PRESSURE COMPARED WITH ADJOINING AREAS; AND ⇒ DO NOT RECIRCULATE THE AIR INSIDE THE PUBLIC FACILITY • EXEMPTS RESTAURANTS (EXCEPT "FAST FOOD" RESTAURANTS), BARS, PRIVATE CLUBS, HOTEL GUEST ROOMS, CASINOS, BINGO PARLORS, TOBACCO MERCHANTS AND PRISONS. • EMPLOYEES MAY NOT BE REQUIRED TO WORK IN SMOKING AREA • DIRECTS OSHA TO ISSUE REGULATIONS ON THE ABOVE STANDARDS, WITH THE TOBACCO INDUSTRY PAYING ENFORCEMENT COSTS. • DOES NOT PREEMPT OR OTHERWISE AFFECT ANY OTHER LOCAL LAW OR REGULATION THAT RESTRICTS SMOKING IN PUBLIC FACILITIES, OR OTHER RULES GOVERNING SMOKING IN FEDERAL AGENCIES • DOES NOT PREEMPT OR OTHERWISE AFFECT ANY OTHER LOCAL LAW OR REGULATION THAT RESTRICTS SMOKING IN PUBLIC FACILITIES, OR OTHER RULES GOVERNING SMOKING IN FEDERAL AGENCIES	ENVIRONMENTAL TOBACCO SMOKE • PROPOSES THAT ALL JURISDICTIONS ENFORCE LEGISLATION AND REGULATIONS TO ELIMINATE EXPOSURE TO ETS BY PROHIBITING SMOKING INCLUDING: ⇒ CONGRESS SHOULD ENACT LEGISLATION TO PROHIBIT SMOKING IN ALL WORK SITES AND IN ALL PLACES OF PUBLIC ASSEMBLY (PRESUMABLY INCLUDING HOSPITALITY VENUES). ⇒ STATE AND LOCAL GOVERNMENTS SHOULD ENACT LEGISLATION AND PROMULGATE REGULATIONS PROHIBITING SMOKING IN ALL WORKPLACES, INCLUDING ALL MILITARY INSTALLATIONS AND VETERANS HOSPITALS ⇒ STATES SHOULD ESTABLISH CLEAN INDOOR AIR LEGISLATION THAT PROHIBITS SMOKING IN ALL PUBLIC PLACES, INCLUDING OUTDOOR AREAS WHERE PEOPLE ASSEMBLE AND CONGREGATE ⇒ STATE AND LOCAL GOVERNMENTS SHOULD PROMULGATE REGULATIONS REQUIRING ALL ELEMENTARY SCHOOLS AND SECONDARY SCHOOL CAMPUSES TO BE 100% SMOKE FREE • PROPOSES THAT CONGRESS ENACT LEGISLATION PROHIBITING SMOKING ON PUBLIC FORMS OF TRANSPORTATION ORIGINATING FROM OR ARRIVING INTO THE U.S. OR ANY OF ITS TERRITORIES • RECOMMENDS THAT CONGRESS NOT PREEMPT STATES' ABILITY TO REGULATE IN THIS AREA

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FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
FOREIGN SALES • NO SPECIFIC PROVISION	FOREIGN SALES • NO SPECIFIC PROVISION	FOREIGN SALES • PROPOSES AN EXECUTIVE ORDER, APPLICABLE TO ALL DEPARTMENTS, WHICH WOULD REQUIRE THE DEPARTMENTS TO ACTIVELY PROMOTE THE GLOBAL ADOPTION OF U.S. DOMESTIC TOBACCO CONTROL POLICIES, AND PROHIBIT DEPARTMENTS FROM INTERFERING WITH EFFORTS TO IMPOSE TOBACCO CONTROLS. ENCOURAGES THE PRESIDENT TO OBTAIN COMMITMENTS FROM THE TOBACCO INDUSTRY TO FOLLOW THE U.S. DOMESTIC REGULATIONS INTERNATIONALLY. PROPOSES A TAX ON NON CONFORMING PRODUCTS.
• NO SPECIFIC PROVISION	• NO SPECIFIC PROVISION	• PROPOSES LEGISLATION AND EXECUTIVE ORDERS INTENDED TO ACCOMPLISH THE DEVELOPMENT, IMPLEMENTATION AND GLOBAL ADOPTION OF THE WHO TOBACCO CONTROL CONVENTION.
• NO SPECIFIC PROVISION	• NO SPECIFIC PROVISION	• PROPOSES U.S. ACTION WHICH WOULD SUPPORT UNICEF EFFORTS GEARED TOWARDS THE ERADICATION OF YOUTH TOBACCO USE.
• NO SPECIFIC PROVISION	• NO SPECIFIC PROVISION	• PROPOSES AMENDING THE 1974 TRADE ACT IN ORDER TO REMOVE TOBACCO PRODUCTS FROM SECTION 301.
• NO SPECIFIC PROVISION	• NO SPECIFIC PROVISION	• PROPOSES FUNDING FOR THE WHO, UNICEF, NON-GOVERNMENT INTERNATIONAL TOBACCO CONTROL COMMISSIONS, AND U.S. AGENCIES, TO PROMOTE TOBACCO CONTROL INTERNATIONALLY.

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VIII. OTHER ISSUES

F . .S PENDING REGULATIONS	PROPOSED SOLUTION	ADVISORY COMMITTEE RECOMMEN .ION
TOBACCO PRICES • NO PROVISION	TOBACCO PRICES • ANNUAL PAYMENTS MADE BY TOBACCO INDUSTRY ARE TO BE REFLECTED IN THE PRICES MANUFACTURERS CHARGE FOR TOBACCO PRODUCTS.	TOBACCO PRICES • RECOMMENDS A NET INCREASE IN THE PRICE OF TOBACCO PRODUCTS, CONSISTENT WITH INFLATION AND EXCISE TAX INCREASES.
HEALTH CARE PROVIDERS • NO PROVISION	HEALTH CARE PROVIDERS • NO PROVISION	HEALTH CARE PROVIDERS • RECOMMENDS DIFFERENTIAL RATES FOR HEALTH, LIFE, AND OTHER RELATED INSURANCE PREMIUMS FOR TOBACCO USERS. • RECOMMENDS THAT INSURANCE COMPANIES, INCLUDING MEDICARE AND MEDICARE, PROVIDE REIMBURSEMENT FOR CESSATION PROGRAMS AS A LIFETIME BENEFIT. • RECOMMENDS DIFFERENTIAL RATES FOR COMPANIES WHICH ALLOW SMOKING IN THE WORKPLACE.
AGRICULTURAL SUPPORTS • NO PROVISION	AGRICULTURAL SUPPORTS • NO PROVISION	AGRICULTURAL SUPPORTS • RECOMMENDS ESTABLISHMENT OF PANEL TO REVIEW DOMESTIC AND INTERNATIONAL TOBACCO GROWING AND PROVIDE STRATEGIES FOR REDUCING DEPENDENCE OF TOBACCO-GROWING STATES ON TOBACCO. • RECOMMENDS ESTABLISHMENT OF ECONOMIC ASSISTANCE AND DEVELOPMENT FUND TO ASSIST FARMERS IN DEVELOPING ALTERNATIVES TO TOBACCO FARMING. • RECOMMENDS ELIMINATION OF TOBACCO PRICE SUPPORT PROGRAMS FOR FARMERS, WITH SUBSIDIES REDIRECTED TO ALTERNATIVE CROPS AND MAINTENANCE OF FAMILY FARMS.

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IX. POLITICAL CONTROLS PLACED UPON THE TOBACCO INDUSTRY

FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
CAMPAIGN FINANCE REFORM • NO PROVISION LOBBYING NO PROVISION	CAMPAIGN FINANCE REFORM • NO PROVISION LOBBYING • REQUIRES TOBACCO COMPANY LOBBYISTS TO SEEK THE MANUFACTURER'S EXPRESS AUTHORIZATION PRIOR TO SUPPORTING OR OPPOSING GOVERNMENTAL ACTION. • REQUIRES THAT LOBBYISTS ARE AWARE OF AND WILL COMPLY WITH: ⇒ APPLICABLE LAWS AND REGULATIONS ⇒ PROVISIONS OF THE AGREEMENT WHICH APPLY TO THEM ⇒ THE CONSENT DECREES; AND ⇒ THE MANUFACTURERS' BUSINESS CONDUCT POLICIES • DISBANDS THE COUNCIL FOR TOBACCO RESEARCH U.S.A. AND THE TOBACCO INSTITUTE, AND PLACES RESTRICTIONS UPON THE FORMATION AND CONDUCT OF NEW TRADE ASSOCIATIONS.	CAMPAIGN FINANCE REFORM • PROPOSES FUNDAMENTAL CAMPAIGN FINANCE REFORM AS A TOBACCO CONTROL POLICY. LOBBYING • RECOMMENDS COMMITMENTS BY THE TOBACCO COMPANIES THAT THEY WILL CEASE LOBBYING RESISTANCE AND WILL ACTIVELY SUPPORT ALL FEDERAL STATE AND LOCAL EFFORTS TO ENFORCE LEGISLATION AND REGULATIONS, PRIOR TO CONGRESS ACCEPTING COMPREHENSIVE LEGISLATION. • RECOMMENDS REQUIRED DISCLOSURE OF TOBACCO COMPANIES' AND THEIR AFFILIATES' PUBLIC RELATIONS, POLITICAL AND OTHER ACTIVITIES.

Source: https://www.industrydocuments.ucsf.edu/docs/yygy0000

FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
STATE ENFORCEMENT INCENTIVES • NO SPECIFIC PROVISIONS (NOTE, HOWEVER, FDA IS PROVIDING FUNDS TO STATES FOR ENFORCEMENT OF FDA RULES VIA CONTRACT.)	STATE ENFORCEMENT INCENTIVES • DENIES FUNDS (PROVIDED BY THE TOBACCO INDUSTRY) TO STATES FAILING TO UNDERTAKE EFFECTIVE ENFORCEMENT STEPS TO REDUCE YOUTH TOBACCO USAGE AND IMPLEMENT YOUTH ACCESS RESTRICTIONS TO TOBACCO PRODUCTS. ENFORCEMENT REQUIREMENTS INCLUDE RANDOM, UNANNOUNCED INSPECTIONS OF RETAILER COMPLIANCE.	STATE ENFORCEMENT INCENTIVES • RECOMMENDS PROVIDING FUNDS, FROM TOBACCO INDUSTRY, TOBACCO LICENSING FEES, TAXES OR SURCHARGES, FOR STATE ENFORCEMENT EFFORTS. SIMILARLY RECOMMENDS COMPLIANCE TESTING THROUGH DECOY "STING" OPERATIONS.
HEALTH CARE • NO SPECIFIC PROVISION	HEALTH CARE • NO SPECIFIC PROVISION	HEALTH CARE • RECOMMENDS EDUCATING HEAL CARE PROVIDERS ABOUT METHODS OF PREVENTING CHILDREN FROM INITIATING TOBACCO USE, AND REQUIRE PROVIDERS TO COUNSEL CHILDREN AND YOUTH ABOUT TOBACCO USE. • RECOMMENDS INCLUDING TOBACCO USE BY CHILDREN AS A FACTOR IN EVALUATING HEALTH CARE SERVICE QUALITY. • RECOMMENDS THAT INQUIRY INTO PARENTAL TOBACCO USE BE A ROUTINE PART OF PRENATAL AND PERIODIC VISITS. • ADVOCATES DEVELOPMENT OF EDUCATIONAL MATERIALS FOR USE BY PARENTS AND CHILDREN IN HOSPITAL, DOCTOR AND DENTIST WAITING ROOMS.

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Source: https://www.industrydocuments.ucsf.edu/docs/yygy0000

FDA'S PENDING REGULATIONS	PROPOSED RESOLUTION	ADVISORY COMMITTEE RECOMMENDATION
TOBACCO IN SCHOOLS • NO SPECIFIC PROVISION (CURRENT LAWS DICTATE)	TOBACCO IN SCHOOLS • NO SPECIFIC PROVISION (CURRENT LAWS DICTATE)	TOBACCO IN SCHOOLS • RECOMMENDS THAT SCHOOLS ADOPT A "ZERO TOLERANCE" POLICY TOWARD TOBACCO USE BY EMPLOYEES AS WELL AS CHILDREN. THIS BAN WOULD EXTEND TO ALL SCHOOL-SPONSORED ACTIVITIES AND INCLUDE A PROHIBITION ON WEARING OR CARRYING PROMOTIONAL ITEMS FOR TOBACCO PRODUCTS. • RECOMMENDS THAT SCHOOLS ADOPT A ZERO TOLERANCE POLICY AGAINST TOBACCO USE WITHIN 200 FEET OF SCHOOL PROPERTY. • RECOMMENDS BANNING SALES (EMPHASIS SUPPLIED) OF TOBACCO PRODUCTS WITHIN 1000 FEET OF SCHOOLS, PLAYGROUNDS AND ANY OTHER AREAS WHERE CHILDREN ASSEMBLE. • RECOMMENDS THAT SCHOOLS IMPLEMENT THE CENTER FOR DISEASE CONTROL GUIDELINES FOR PREVENTING TOBACCO USE AND DEPENDENCE AND INSTITUTE TOBACCO PREVENTION PROGRAMS IN PRE K THROUGH 12TH GRADE. • ADVOCATES DEVELOPMENT OF PUBLIC-PRIVATE PARTNERSHIPS WITH BUSINESSES TO SPONSOR ANTI-SMOKING MEDIA CAMPAIGNS AND NON-SMOKING EVENTS. • RECOMMENDS THAT SCHOOLS FACILITATE CESSATION PROGRAMS FOR STUDENTS, FACULTY AND STAFF.

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